

EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 69 OF 2017

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – October 2017 reduction day) Amendment Determination 2017 (No.1)

Authority

This legislative instrument is made pursuant to subsection 99ADB(4) of the *National Health Act 1953* (the Act), which provides that the Minister may, by legislative instrument, determine the weighted average disclosed price (WADP) of a brand of a pharmaceutical item (listed brand) in accordance with the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations).

Subsection 99ADB(7) of the Act further provides that a subsection 99ADB(4) determination for a listed brand may include the adjusted approved ex-manufacturer price (AAEMP) for the listed brand.

Purpose

This legislative instrument amends the *National Health (Weighted average disclosed price – October 2017 reduction day) Determination 2017* (PB 44 of 2017) (the Principal Instrument) by:

- amending the WADPs for brands of pharmaceutical items containing perindopril for oral administration (perindopril), perindopril with amlodipine for oral administration (perindopril with amlodipine), perindopril with indapamide for oral administration (perindopril with indapamide) and topotecan for administration by injection (topotecan);
- revoking the WADPs for all brands of pharmaceutical items containing carboplatin for administration by injection (carboplatin), docetaxel for administration by injection (docetaxel), gemcitabine for administration by injection (gemcitabine), oxaliplatin for administration by injection (oxaliplatin) and methotrexate for administration by injection (methotrexate);
- amending the WADPs for all brands of the following 13 pharmaceutical items that no longer meet the no reduction criteria under regulation 82:
 - Filgrastim, Injection 120 micrograms in 0.2 mL single use pre-filled syringe (Nivestim), Injection;
 - Filgrastim, Injection 300 micrograms in 1 mL, Injection ;
 - Filgrastim, Injection 480 micrograms in 0.8 mL single use pre-filled syringe (TevaGrastim), Injection;
 - Filgrastim, Injection 480 micrograms in 1.6 mL, Injection;
 - Olanzapine, Tablet 10 mg (as benzoate), Oral;
 - Olanzapine, Tablet 5 mg (as benzoate), Oral;
 - Olanzapine, Tablet 7.5 mg (as benzoate), Oral;
 - Ondansetron, Wafer 8 mg, Oral;
 - Pramipexole, Tablet (extended release) containing pramipexole hydrochloride 375 micrograms, Oral;

- Pramipexole, Tablet (extended release) containing pramipexole hydrochloride 750 micrograms, Oral;
- Tamoxifen, Tablet 10 mg (as citrate), Oral;
- Topiramate, Capsule 25 mg, Oral; and
- Topiramate, Capsule 50 mg, Oral;
- inserting a WADP for the first new brand of the following new pharmaceutical item:
 - Ursodeoxycholic acid, Tablet 500 mg, Oral.

The Principal Instrument was made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for brands of pharmaceutical items with a data collection period ending 31 March 2017 (2017 October cycle).

Amendments

Perindopril, Perindopril with Amlodipine, Perindopril with Indapamide and Topotecan
Amendments are being made following consideration of matters raised by responsible persons concerning the determinations in the Principal Instrument for brands of pharmaceutical items containing perindopril, perindopril with amlodipine, perindopril with indapamide and topotecan. A review of determinations in response to matters raised by responsible persons revealed that incorrect data had been submitted by some responsible persons. Corrected data was submitted by some responsible persons for certain brands containing the drugs set out above. New calculations for the WADPs set out in this amending determination were completed in accordance with the Act and Regulations.

This amending instrument removes the previous WADPs for brands of perindopril, perindopril with amlodipine, perindopril with indapamide and topotecan. Revised WADPs for brands of perindopril are inserted in the appropriate column in Schedule 1 and revised WADPs for brands of perindopril with amlodipine, perindopril with indapamide and topotecan are inserted in Schedule 2.

Listed brands of perindopril are included in Schedule 1 of the Principal Instrument because they continue to have an unadjusted price reduction of at least 10 per cent. Listed brands of perindopril with amlodipine, perindopril with indapamide and topotecan are inserted in Schedule 2 of the Principal Instrument because their unadjusted price reduction following determination of the amended WADP is less than 10%.

For those brands with a WADP re-inserted in Schedule 1, the same amount is also determined as the AAEMP for the brands due to the operation of section 7 of the Principal instrument. A Responsible Person for a listed brand appearing in Schedule 1 of the Principal Instrument will receive a price disclosure reduction on and from 1 October 2017, provided that, on that date, the 'approved ex-manufacturer price' for the listed brand is more than the determined 'AAEMP' for that brand.

Revocation of WADPs

This amending instrument revokes the WADPs in the Principal Instrument for:

- all brands of carboplatin, docetaxel, gemcitabine and oxaliplatin because brands of these drugs received a price increase on 1 December 2016, during the data collection period for the Cycle; and
- for methotrexate to support sustainable pricing and continued access to this drug/MoA for Australian patients.

As a result of the amending instrument no price disclosure reduction will apply to any brand of carboplatin, docetaxel, gemcitabine, oxaliplatin or methotrexate on 1 October 2017.

Amending the WADP for brands that no longer meet Regulation 82

WADPs/AAEMPs are being determined for all brands of 13 pharmaceutical items that no longer meet the criteria under regulation 82. The applicable PBS price that was determined as the WADP for these brands is being omitted and a new reduced price for each brand is being inserted into Schedule 1 because the unadjusted price reduction for these brands is now 10% or greater.

Insertion of WADP determinations for New Brands of New Pharmaceutical Items

A WADP is required to be determined for new brands of pharmaceutical items listing between 1 July 2017 and 1 September 2017 that have no other existing brand of the same pharmaceutical item (including a single brand pharmaceutical item where the brand or pharmaceutical item changes, or where all existing brands change).

There is one brands of one new pharmaceutical item that is included in this amending instrument, as follows:

- the Ursofalk[®] brand of ‘ursodeoxycholic acid, tablet 500 mg, oral’.

Basis for amendments

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to vary or revoke the determination made under subsection 99ADB(4) for the medicines affected by this amending instrument.

Consultation

This instrument affects companies that are Responsible Persons for brands of pharmaceutical items containing perindopril, perindopril with amlodipine, perindopril with indapamide, toptecan, carboplatin, docetaxel, gemcitabine, oxaliplatin and methotrexate.

Further, it affects companies that are Responsible Persons for brands of the following pharmaceutical items:

- Filgrastim, Injection 120 micrograms in 0.2 mL single use pre-filled syringe (Nivestim), Injection;
- Filgrastim, Injection 300 micrograms in 1 mL, Injection ;
- Filgrastim, Injection 480 micrograms in 0.8 mL single use pre-filled syringe (TevaGrastim), Injection;
- Filgrastim, Injection 480 micrograms in 1.6 mL, Injection;
- Olanzapine, Tablet 10 mg (as benzoate), Oral;
- Olanzapine, Tablet 5 mg (as benzoate), Oral;
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- Pramipexole, Tablet (extended release) containing pramipexole hydrochloride 375 micrograms, Oral;
- Pramipexole, Tablet (extended release) containing pramipexole hydrochloride 750 micrograms, Oral;
- Tamoxifen, Tablet 10 mg (as citrate), Oral;
- Topiramate, Capsule 25 mg, Oral;

- Topiramate, Capsule 50 mg, Oral; and
- Ursodeoxycholic acid, Tablet 500 mg, Oral.

All of the affected companies were consulted about the amendments. No concerns were expressed.

This instrument commences on the day after it is registered on the Federal Register of Legislation. This instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011
National Health (Weighted average disclosed price – October 2017 reduction day)
Amendment Determination 2017 (No.1)

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

This instrument amends the *National Health (Weighted average disclosed price – October 2017 reduction day) Determination 2017* (the Principal Instrument) to: a) adjust the weighted average disclosed prices for brands of perindopril, perindopril with amlodipine, perindopril with indapamide and topotecan calculated using corrected data provided by companies; b) revoke price reduction determinations to preserve the effect of price increases that were granted during the price disclosure cycle and to support sustainable pricing and continued access for Australian patients; c) insert new reduced prices for all brands of 13 pharmaceutical items that no longer meet the no reduction criteria under regulation 82 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations); and d) insert the price for a new brand of new pharmaceutical item.

Part VII of the Act is the legislative basis for the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Part VII, Division 3B of the *National Health Act 1953* (the Act) deals with price disclosure. Price disclosure provides for the ‘approved ex-manufacturer price’ of a ‘brand of a pharmaceutical item’ to be reduced on a reduction day in certain specified circumstances. The reduction is based on sales revenue, incentives and volume data collected from Responsible Persons (drug companies) and occurs in accordance with the Act and the Regulations.

The amendments are made to provide for correct and effective reductions in prices for pharmaceutical benefits on 1 October 2017 under the statutory provisions for price disclosure.

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines.

The price disclosure program progressively reduces the price of some PBS medicines which are subject to competition, ensuring better value for money from these medicines. These reductions may also result in patients accessing these medicines at lower prices.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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